

# **EXHIBIT A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC.	)	
and SCR PHARMATOP,	)	
	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. 11-733 (LPS)(MPT)
PADDOCK LABORATORIES, INC.;	)	
PERRIGO COMPANY; PADDOCK	)	
LABORATORIES, LLC; EXELA PHARMA	)	
SCIENCES, LLC; EXELA PHARMSCI, INC.;	)	
and EXELA HOLDINGS, INC.;	)	
	)	
Defendants.	)	

**PLAINTIFF CADENCE PHARMACEUTICALS, INC.'S RESPONSES AND  
OBJECTIONS TO DEFENDANTS EXELA PHARMA SCIENCES, LLC; EXELA  
PHARMSCI, INC. AND EXELA HOLDINGS, INC.'S SECOND SET OF  
INTERROGATORIES (Nos. 4-5)**

Pursuant to FEDERAL RULE OF CIVIL PROCEDURE 33 and Local Civil Rule 26.1, Plaintiff Cadence Pharmaceuticals, Inc. ("Cadence") hereby responds to defendants Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc.'s (collectively, "Exela") Second Set of Interrogatories (Nos. 4-5) ("Interrogatories").

Pursuant to FEDERAL RULE OF CIVIL PROCEDURE 26(e), Cadence reserves the right to supplement its responses or document production under FEDERAL RULE OF CIVIL PROCEDURE 33(d).

**GENERAL OBJECTIONS**

Cadence makes its following General Objections to Exela's Second Set of Interrogatories (Nos. 4-5), which General Objections are hereby incorporated by reference and made part of its response to each and every interrogatory. Cadence's General Objections to Exela's First, Second, Third, Fourth, and Fifth Set of Document Requests (Nos. 1-125), and to

asserted claims. Cadence reserves its right to amend or supplement its response to this interrogatory as discovery proceeds and/or after the Court issues a claim construction position.

**1. Part 1—Infringement of the '222 Patent**

Subject to and without waiving the foregoing objections, Cadence further responds that the product described in Exela's ANDA and/or submission of ANDA No. 20-3092 infringe at least claims 1-5, 9, 10, 12, 14, and 16-18 of the '222 Patent, either literally or under the doctrine of equivalents. The details of the bases for Cadence's infringement contentions of the '222 Patent are set forth in Appendix A. Cadence further states that, pursuant to FED. R. CIV. P. 33(d), the answer to Interrogatory No. 4, Part 1 can be derived or ascertained from documents labeled EXELA-00000001-1579.

**2. Part 2—Infringement of the '218 Patent**

Subject to and without waiving the foregoing objections, Cadence further responds that the product and methods of manufacture described in Exela's ANDA and/or submission of ANDA No. 20-3092 infringe at least claims 1, 3, 4, 8, 9, and 19 of the '218 Patent, either literally or under the doctrine of equivalents. The details of the bases for Cadence's infringement contentions of the '218 Patent are set forth in Appendix B. Cadence further states that, pursuant to FED. R. CIV. P. 33(d), the answer to Interrogatory No. 4, Part 2 can be derived or ascertained from documents labeled EXELA-00000001-1579.

**INTERROGATORY NO. 5:**

Describe with full particularity all facts referring or relating to any assertion by Plaintiffs that the claims of the patents-in-suit are not anticipated and/or not obvious for the reasons set forth by Exela in its notice letter and/or in Exela's response to plaintiffs' interrogatories, including any alleged secondary considerations of nonobviousness. This detailed description shall include, without limitation, (a) a claim chart for each reference identified by Exela in its notice letter or in its response to plaintiffs' interrogatory number 2, showing the presence or absence of each claim element of each claim of the patents-in-suit in each reference,

and (b) an identification of any document, information, or tangible item that supports, refutes, or otherwise concerns Your contentions.

**RESPONSE TO INTERROGATORY NO. 5:**

Cadence incorporates its General Objections as and for its objections to Interrogatory No. 5. Cadence further objects to this Interrogatory to the extent that it calls for material that is protected from discovery by the attorney-client privilege, the work product doctrine, Federal Rule of Civil Procedure 26(b)(4), the common interest privilege, and/or any other applicable privilege or immunity. Cadence further objects to this interrogatory as being vague and ambiguous with respect to “each reference identified by Exela.” Cadence further objects to this interrogatory as being vague and ambiguous with respect to “the reasons set forth by Exela in its notice letter and/or in Exela’s response to plaintiffs’ interrogatories” as these sources do not clearly separate or articulate Exela’s analysis of anticipation and obviousness. Cadence further objects to this Interrogatory on the grounds that it is compound and contains multiple subparts constituting separate interrogatories. Cadence further objects to this interrogatory as overly broad and unduly burdensome on the grounds it seeks Cadence’s contentions regarding both anticipation and obviousness by way of a “claim chart for each reference identified by Exela” and “identification of any document, information, or tangible item.” Cadence further objects to this interrogatory on the grounds that it improperly attempts to shift the burden of proving validity to Cadence. The patents-in-suit are presumed valid under 35 U.S.C. § 282, and it is Exela’s burden to prove invalidity. Cadence further objects to this Interrogatory as premature for requesting Cadence’s contentions while fact discovery is ongoing and expert discovery has yet to commence. Cadence further objects to this interrogatory as premature in that the Court has not construed the terms of the asserted claims. Cadence reserves

of Allowance. The United States Patent and Trademark Office specifically considered the '222 Patent as a prior art reference and determined that the claims of the '218 Patent were patentable over it. Accordingly, Exela's burden of proof concerning invalidity is even higher, and Exela has failed to meet its burden.

The Notice Letter also asserts that claims 3-4, 8-9, and 16-19 are obvious in view of the '222 Patent in combination with other prior art references. Specifically, the Notice Letter includes a claim chart allegedly showing that claims 3 and 4 are obvious over the '222 Patent in combination with the Palmieri Article, and that claims 8 and 9 are obvious over the '222 Patent standing alone. Cadence states that claims 3, 4, 8, 9 and 19 of the '218 Patent are not obvious in view of the '222 Patent at least for the reasons cited by the Examiner during the prosecution of the '218 Patent. *See, e.g.*, June 10, 2005 Notice of Allowance. Further, because claim 1 is not obvious, the remaining dependent claims are not obvious, either. Moreover, there was no motivation to combine the '222 patent with any other reference to obtain the subject matter of claim 1 (let alone the dependent asserted claims). Exela also alleges that claim 19 is obvious for the same reasons Exela maintains claim 1 is obvious. As described above, claim 1 is not obvious. Accordingly, Claim 19 is not obvious for the same reasons that claim 1 is not obvious.

#### **5. Part 5—Secondary Considerations Nonobviousness of the '222 Patent**

Subject to and without waiver of the General and Specific Objections, and based on current information, Cadence states the claims of the patents-in-suit are presumed valid. Defendants bear the burden of proving invalidity by clear and convincing evidence. Defendants have not met their burden. As noted in response to Interrogatory No. 5, Part 3, a person of ordinary skill in the art would not have had a reasonable expectation of successfully preparing aqueous formulations of acetaminophen suitable for pharmaceutical use. However, even if a

Court were to conclude that the formulation of acetaminophen was *prima facie* obvious, Cadence states that there are secondary consideration that support the non-obviousness of the claims of the patents-in-suit. Such secondary considerations of non-obviousness include at least commercial success, long-felt but unresolved needs, failure of others, industry acquiescence, teaching away by others, and copying of the invention.

The commercial success of the claimed invention is demonstrated by, for example, the rapid acceptance of OFIRMEV® by U.S. formularies and substantial sales of OFIRMEV®. For example, as of October 31, 2011, OFIRMEV® had achieved formulary acceptance at over 1,400 U.S. hospital formularies, and as of December 31, 2011, OFIRMEV® had achieved formulary acceptance at approximately 1,580 U.S. hospital formularies. *See* “Cadence Pharmaceuticals Reports Third Quarter 2011 Financial Results,” available at: <http://investors.cadencepharm.com/redesign/releases.cfm> and CADX-0156672-701. Since its launch in January 2011, sales of OFIRMEV® reached over \$3.5 million by the third quarter of 2011. *See* “Cadence Pharmaceuticals Reports Third Quarter 2011 Financial Results,” available at: <http://investors.cadencepharm.com/redesign/releases.cfm>. Because OFIRMEV® is the only aqueous pharmaceutical formulation of acetaminophen approved for sale by the FDA that is suitable for injection and it practices one or more claims of the claims of the patents-in-suit, Plaintiffs have established a *prima facie* case for a nexus between the claimed invention of the patents-in-suit and the commercial success of OFIRMEV®. *Crocs, Inc. v. ITC*, 598 F.3d 1294, 1310-11 (Fed. Cir. 2010); *see also Alza Corp. v. Andrx Pharm., LLC*, 607 F. Supp. 2d 614, 644 (D. Del. 2009).

The commercial success of the claimed invention is also supported by the rapid and widespread sales of Perfalgan®. *See, e.g.,* CADX0156672-701; CADX0724135;

CADX1057279-81. Worldwide sales of patented inventions are evidence of commercial success. *See Lindemann Mascinefabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984) (finding that the district court erred in discounting the weight due to evidence of commercial success because that success had occurred abroad). Based on Cadence's understanding that Perfalgan® also embodies one or more claims of the patents-in-suit, this evidence also establishes a prima facie case of a nexus between the claimed invention of the patents-in-suit and the commercial success of Perfalgan®. *Crocs, Inc. v. ITC*, 598 F.3d 1294, 1310-11 (Fed. Cir. 2010); *see also Alza Corp. v. Andrx Pharm., LLC*, 607 F. Supp. 2d 614, 644 (D. Del. 2009).

Industry acquiescence is demonstrated by at least the fact that several entities have licensed the patents-in-suit. For example, UPSA, Bristol-Meyers Squibb Company and Cadence each obtained a license to the patents-in-suit. *See, e.g.*, D.I. 1, ¶¶ 27-28; PHARM0003316-378; CADX-1447177-259. Additionally, Terumo Corporation obtained a license one or more foreign counterparts to the patents-in-suit for the rights to develop and manufacture the same intravenous formulation of acetaminophen in Japan. *See, e.g.*, PHARM0000289-331; PHARM0000528-575. Moreover, the status of Bristol-Meyers Squibb Company as a leader in the pharmaceutical industry at the time of the license is additional evidence of industry acquiescence. *Trustees of Columbia Univ. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90, 110 (D. Mass. 2002) (citing *Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1575 (Fed.Cir.1992)).

The aqueous pharmaceutical formulations embodied by or produced according to the claims of the patents-in-suit satisfied a long-felt need in the area of post-operative pain management. For example, previously available opioids and NSAIDs possess many negative

characteristics that make them undesirable for post-surgery pain management. Among these negative characteristics are the increased risk of addiction, respiratory depression, nausea, and various gastrointestinal side effects. In addition, patients typically are unable to receive non-intravenous formulations, such as oral formulations, immediately post-operation. The FDA's decision to grant the NDA for OFIRMEV® priority review – which is granted for products that address significant unmet medical needs – further demonstrates that OFIRMEV® has met a long-felt but unresolved need.

The failure of others to solve the long-felt need addressed by the claimed inventions of the patents-in-suit likewise supports non-obviousness. For example, the previously developed injectable acetaminophen pro-drug Pro-Dafalgan® possessed many negative side effects that rendered the drug unsatisfactory. Pro-Dafalgan was known to cause mild to moderate pain in the arm from the injection site to the shoulder upon IV injection. *See, e.g.*, CADX-0062940-943. Furthermore, the drug was dangerous to the healthcare professionals administering the drug to patients. *See, e.g.*, CADX-0065635-638. In addition, the drug Apotel® is an example of another failure to solve the long-felt need addressed by the claimed invention of the patents-in-suit. Apotel® is a formulation of acetaminophen for intramuscular injection. Among other problems with the formulation, the formulation is so painful upon administration that it is formulated with lidocaine to help minimize the pain caused by injection of the product. *See* Fassoulaki et al., “The Analgesic Effect of Gabapentin and Mexiletine After Breast Surgery for Cancer” 95 *Anesth. Analg.* 985, 986 (2002) (“Fassoulaki 2002”).

Prior art references taught away from the aqueous solutions reflected in the claims of the patents-in-suit. For example, prior art references taught the mixture of acetaminophen and polyethylene glycol. *See, e.g.*, Yan et al., Report on the Research and Production of Paracetamol



Injection (“Yan”) and Korean Patent No. KR9311994 (“Kim”). Such compositions are not aqueous solutions.

Copying by others is demonstrated at least by the Paddock ANDA product and the Exela ANDA Product.

Cadence understands Perfalgan® to be a European embodiment of the patents-in-suit, approved for use in Europe in 2001. Pursuant to Fed. R. Civ. P. 33(d), Cadence further identifies the following documents produced in this action: CADX-0015764-878; CADX-0017167-231; CADX-0018438-449; CADX-0107382-388; CADX-0122651-692.

**6. Part 6—Secondary Considerations of Nonobviousness of the ’218 Patent**

Cadence’s Response to Interrogatory No. 5, Part 5, is hereby incorporated by reference and made part of its response to Interrogatory No. 5, Part 6. In addition, Cadence states that the prolonged pharmaceutically acceptable shelf life enabled by practicing claim 1 and/or 19 of the ’218 patent itself satisfied a long-felt need and that the commercial success of both Ofirmev® and Perfalgan® has been enhanced by having a prolonged pharmaceutically acceptable shelf life. In addition, Paddock and Exela have both copied the subject matter of at least claim 19 of the ’218 patent for purposes of requesting a prolonged shelf-life approval from the FDA. *See* EXELA-00000525.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Thomas C. Grimm*

OF COUNSEL:

Stephen P. Swinton  
Darryl H. Steensma  
LATHAM & WATKINS LLP  
12636 High Bluff Drive, Suite 400  
San Diego, CA 92130  
(858) 523-5400

Kenneth G. Schuler  
Marc N. Zubick  
LATHAM & WATKINS LLP  
233 South Wacker Drive, Suite 5800  
Chicago, IL 60606  
(312) 876-7700

Melissa A. Kopacz  
LATHAM & WATKINS LLP  
140 Scott Drive  
Menlo Park, CA 94025  
(650) 328-4600

*Attorneys for Plaintiff Cadence  
Pharmaceuticals, Inc.*

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Jack B. Blumenfeld (#1014)  
Thomas C. Grimm (#1098)  
Jeremy A. Tigan (#5239)  
1201 N. Market Street  
P.O. Box 1347  
Wilmington, DE 19899-1347  
(302) 658-9200  
jblumenfeld@mnat.com  
tgrimm@mnat.com  
jtigan@mnat.com  
*Attorneys for Plaintiff Cadence  
Pharmaceuticals, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on August 16, 2012, copies of the foregoing were caused to be served upon the following in the manner indicated:

**BY E-MAIL**

Adam W. Poff  
Pilar G. Kraman  
YOUNG CONAWAY STARGATT & TAYLOR, LLP  
Rodney Square  
1000 N. King Street  
Wilmington, DE 19801  
*Attorneys for Exela Pharma Sciences, LLC,  
Exela PharmSci, Inc. and Exela Holdings, Inc.*

Allen A. Arntsen  
FOLEY & LARDNER LLP  
150 East Gilman Street  
Madison, WI 537803  
*Attorneys for Exela Pharma Sciences, LLC,  
Exela PharmSci, Inc. and Exela Holdings, Inc.*

Michael Houston  
FOLEY & LARDNER LLP  
321 North Clark Street, Suite 2800  
Chicago, IL 60654  
*Attorneys for Exela Pharma Sciences, LLC,  
Exela PharmSci, Inc. and Exela Holdings, Inc.*

Liane M. Peterson  
FOLEY & LARDNER LLP  
3000 K Street, N.W., Suite 6000  
Washington, DC 20007  
*Attorneys for Exela Pharma Sciences, LLC,  
Exela PharmSci, Inc. and Exela Holdings, Inc.*

/s/ Thomas C. Grimm

Thomas C. Grimm (#1098)

## **EXHIBIT B**



November 28, 2012

## **Cadence Pharmaceuticals Announces Settlement of OFIRMEV® (Acetaminophen) Injection Patent Litigation with Perrigo Company**

SAN DIEGO, Nov. 28, 2012 /PRNewswire/ -- Cadence Pharmaceuticals, Inc. (Nasdaq: CADX) today announced that it has entered into settlement and license agreements with Perrigo Company (Nasdaq: PRGO; TASE), and its subsidiary, Paddock Laboratories, LLC, to resolve pending patent litigation involving OFIRMEV® (acetaminophen) injection.

The settlement agreement includes a stipulation by the parties requesting dismissal with prejudice of the lawsuit filed by Cadence in the U.S. District Court for the District of Delaware relating to the Abbreviated New Drug Application, or ANDA, filed by Paddock with the U.S. Food and Drug Administration for a generic version of OFIRMEV® (acetaminophen) injection. Litigation remains ongoing against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc.

Under the license agreement, Perrigo has been granted the exclusive right of first refusal to negotiate an agreement with Cadence to market an authorized generic version of OFIRMEV (i.e., a generic version marketed under Cadence's New Drug Application) in the U.S., in the event that Cadence elects to launch an authorized generic version of the product. Additionally, Cadence has granted Perrigo the non-exclusive right to market a generic intravenous acetaminophen product in the U.S. under Perrigo's ANDA, after December 6, 2020, or earlier under certain circumstances. Currently, Cadence has listed two Orange Book patents covering OFIRMEV, the last of which, U.S. Patent No. 6,992,218, will expire on June 6, 2021, or December 6, 2021, if pediatric exclusivity is granted.

The license agreement also provides that, if the parties enter into an agreement for Perrigo to market an authorized generic version of OFIRMEV, during the license period, Perrigo would purchase the product exclusively from Cadence. Cadence would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Other details of the settlement are confidential, and the agreements are subject to submission to the Federal Trade Commission and the U.S. Department of Justice. The settlement and license agreements will become effective upon the entry by the U.S. District Court for the District of Delaware of an order dismissing with prejudice the litigation with respect to Perrigo.

"This settlement validates our confidence in the integrity of the patents covering OFIRMEV," said Ted Schroeder, President and CEO of Cadence. "We believe that OFIRMEV is an important medication for managing pain and fever in hospitalized patients, and we look forward to years of continued growth in sales of this product."

### **About OFIRMEV® (Acetaminophen) Injection**

OFIRMEV (acetaminophen) injection (1000 mg / 100 mL, 10 mg / mL; for intravenous use only), Cadence Pharmaceuticals' proprietary intravenous formulation of acetaminophen, is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever. The FDA approval of OFIRMEV was based on data from clinical trials in approximately 1,020 adult and 355 pediatric patients. These trials included two studies evaluating the safety and effectiveness of OFIRMEV in the treatment of pain, and one study evaluating OFIRMEV in the treatment of fever. The effectiveness of OFIRMEV for the treatment of acute pain and fever has not been studied in pediatric patients less than 2 years of age.

### **Important Safety Information**

Do not exceed the maximum recommended daily dose of acetaminophen. Administration of acetaminophen by any route in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. OFIRMEV is contraindicated in patients with severe hepatic impairment, severe active liver disease or with known hypersensitivity to acetaminophen or to any of the excipients in the formulation. Acetaminophen should be used with caution in patients with the following conditions: hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia, or severe renal impairment. OFIRMEV should be administered only as a 15-minute intravenous infusion. Discontinue OFIRMEV immediately if symptoms associated with allergy or hypersensitivity occur. Do not use in patients with acetaminophen allergy. The most common adverse reactions in patients treated with OFIRMEV were nausea, vomiting, headache, and insomnia in adult patients and nausea, vomiting, constipation, pruritus, agitation, and atelectasis in pediatric patients. The antipyretic effects of OFIRMEV may mask fever in patients treated for post-surgical pain.

For more information, please see the complete OFIRMEV Prescribing Information, available at [www.OFIRMEV.com](http://www.OFIRMEV.com) or

## About Cadence Pharmaceuticals, Inc.

Cadence Pharmaceuticals is a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. The current version of Cadence Pharmaceuticals' corporate overview may be viewed on the Investors page of [www.cadencepharm.com](http://www.cadencepharm.com) under "Events & Presentations" by selecting "Corporate Overview."

## Forward-Looking Statements

Statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "plans," "believes," "expects," "anticipates," and "will," and similar expressions, are intended to identify forward-looking statements, and are based on Cadence's current beliefs and expectations. Such statements include, without limitation, statements regarding the potential for approval of the settlement terms by the U.S. District Court for the District of Delaware, the Federal Trade Commission and the U.S. Department of Justice; our confidence in the strength of the patents covering OFIRMEV and the prospects for future growth in sales of the product; and the prospect of Cadence receiving payments from Paddock, including product costs, an administrative fee and royalty payments. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cadence's actual future results may differ materially from Cadence's current expectations due to the risks and uncertainties inherent in its business. These risks include, but are not limited to: Cadence's dependence on the successful commercialization of OFIRMEV, which is currently the company's only product, including its ability to achieve broad market acceptance and generate revenues from sales of OFIRMEV; Cadence's ability to successfully enforce its marketing exclusivities and intellectual property rights, and to defend the patents covering OFIRMEV, including in current patent litigation with Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., or collectively, Exela; the potential that Cadence may be required to continue patent litigation for substantial lengths of time, file additional lawsuits to defend its patent rights from challenges by Exela or other companies that may submit ANDAs for generic versions of OFIRMEV, and the substantial costs associated with such lawsuits; the potential that the United States Patent and Trademark Office, or USPTO, may not prevail in a lawsuit filed against it earlier this year by Exela in the United States District Court for the Eastern District of Virginia, in which Exela seeks a reversal of the USPTO's decision to refuse to act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international application for U.S. Patent No. 6,992,218; the potential that the USPTO may grant an ex parte request for the reexamination of U.S. Patent No. 6,028,222, and that, as a result of such reexamination, claims in that patent may be invalidated or narrowed in scope; the potential introduction of generic competition to OFIRMEV in the event Cadence is unsuccessful in current or future patent litigation; Cadence's dependence on its licensors for the maintenance and enforcement of its intellectual property rights; the potential product liability exposure associated with pharmaceutical products such as OFIRMEV and other products Cadence may in-license or acquire; Cadence's ability to ensure an adequate and continued supply of OFIRMEV to meet anticipated market demand; and the risk that Cadence may not be able to raise sufficient capital when needed, or at all; and other risks detailed under "Risk Factors" and elsewhere in Cadence's periodic reports and other filings made with the SEC from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, and the company undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

Cadence<sup>®</sup> and OFIRMEV<sup>®</sup> are trademarks of Cadence Pharmaceuticals, Inc.

Contact:	William R. LaRue	Kelli France
	SVP & Chief Financial Officer	Media Relations
	Cadence Pharmaceuticals, Inc.	WCG
	Phone: 858-436-1400	Phone: 415-946-1076

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## **EXHIBIT C**

**Cadence Pharmaceuticals, Inc.***Company▲*

CADX

*Ticker▲*

Piper Jaffray Healthcare

Conference

*Event Type▲*

Nov. 28, 2012

*Date▲***— PARTICIPANTS****Corporate Participants****Theodore R. Schroeder** – President, Chief Executive Officer & Director**Other Participants****Traver A. Davis** – Analyst, Piper Jaffray, Inc.**— MANAGEMENT DISCUSSION SECTION****Traver A. Davis, Analyst, Piper Jaffray, Inc.**

All right, let me get started? My name is Traver Davis. I'm a member of the Specialty Pharmaceuticals Team here at Piper Jaffray led by David Amsellem.

Our next presentation will be from Cadence Pharmaceuticals and with us today we have CEO, Ted Schroeder. Thanks for joining us.

So why don't we just quickly start with, Ted, if you could just give us sort of a brief quick background of the company and then also maybe a little bit more color on this morning's news?

**Theodore R. Schroeder, President, Chief Executive Officer & Director**

Sure. Sure. Glad to. So good morning, everyone, thanks for joining us. Cadence Pharmaceuticals, we're a specialty pharmaceutical company focused in the hospital space. We have a single commercial product IV acetaminophen brand name OFIRMEV that we sell to hospitals in the United States for patients who are unable to take and absorb oral medication so mostly for perioperative pain, but generally for pain and fever across the hospital when patients are unable to reliably swallow. We have a 130-person sales force that supports that product and we call on just under 1,800 hospitals across the United States.

So we launched the product in January 2011 so we're coming up on our second year on the market. Annualized sales as of October would come in at about \$72 million and growing from there. So, it's a growing product and a product that we expect will ultimately become the standard of care in a multi-modal approach to managing pain in the hospital. As you might know, there are quite a few market dynamics that are pushing hospitals to reduce the number of narcotics they use across wide varieties of patients and a movement toward our multi-modal pain relief, certainly a firm that plays a big role in that process.

When you use IV acetaminophen as the first pain drug on board, you see anywhere from a 33% to an 82% reduction in narcotic use and that comes with superior pain control. So you not only see fewer narcotic doses taken by the patient, but you actually get better patient pain relief scores at the same time. And you could think of that, it might seem a little counterintuitive, is acetaminophen as potent as a narcotic. The answer is no, it's not; but it's actually the synergy between the two products attacking different pain receptors. And you can think about it as an approach in a setting where patients can't swallow, similar to taking Vicodin in the oral setting, which is a combination of a narcotic and acetaminophen. The advantage here is that you can dial the narcotic up and down and really treat to the patient's level of pain. It's not a fixed dose.



**Cadence Pharmaceuticals, Inc.***Company▲*

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Piper Jaffray Healthcare

Conference

*Event Type▲*

Nov. 28, 2012

*Date▲*

So I'll stop there by way of background. This morning we announced that we settled with Perrigo with one of our Phase IV – excuse me – one of our Paragraph IV filers for a ANDA. I think the highlights of that settlement are that we settled for they can't bring a generic to the market before December 6, 2020. I think that's well beyond what most people were assuming. There are two patents that cover OFIRMEV, a formulation patent that expires in 2018 and a process patent that expires in June 2021 so they've essentially agreed to six months off of that patent.

We also entered into an agreement and gave them the right of first refusal to be our authorized generic. The important headline there is that's at our discretion. So if we believe that it would be important to bring an authorized generic to market, Perrigo has the right of first refusal, but there's nothing in the agreement that would force us to bring an authorized generic to market.

There is a second Paragraph IV filer, a small private generic company called Exela, and so the bench hearing for that Paragraph IV is scheduled for May and we continue to work through the process with Exela and we'll see what happens after today's announcement. So we're very pleased with the announcement. We think it validates our patents and the strength of patents as we've outlined them all along and with us a legitimate player in the generic field, I think it's a really good settlement for both them and for us.

**Traver A. Davis, Analyst, Piper Jaffray, Inc.**

Great, thanks. So why don't we just – a follow-up question to the settlement. So you told us there's one other additional filer, but I believe there are some manufacturing and formulation hurdles that form the basis of the IP. So can you just take us through what you believe to be novel about the IV formulation and what could possibly explain why now with the agreement announced this morning, we're not seeing a generic until 2020?

**Theodore R. Schroeder, President, Chief Executive Officer & Director**

Yeah. So the reason there hasn't been an IV acetaminophen on the market before now isn't because no one thought of it. I think this is fairly a obvious product that there'd be a lot of need for in hospitalized patients. The problem's been actually doing it, getting the product into a solution that was stable and many, many companies tried over decades to crack that code, including J&J that tried for 30 plus years to get a stable IV formulation and weren't able to do it. The two French scientists who cracked the code, they call themselves Pharmatop, own the worldwide IP for the product and we have a sub-license to that IP in the US and Canada.

The essential invention is that the Pharmatop folks recognize that as acetaminophen is degraded by oxygen, it forms free radicals and those free radicals act as catalysts and so as the product degrades; the oxygen creates free radicals, the free radicals act as catalysts, and the chemical process becomes ever more efficient as the product degrades and so you need to do two things. The formulation patent included the introduction of free radical scavengers and radical antagonists, they basically soak up all the free radicals and stabilize the formulation. That patent covers all excipients used as radical scavengers or radical antagonists.

So that's the strength of what's known as the 218 patent. It's really around free radical scavenging. And the patent is so broad that there really are no other choices. All the current [ph] brass listed (07:36) excipients are included, but even if you invented a new one, it would still fall under the patent. And so I think most people are pretty comfortable that the 218 patent was pretty solid.

**Cadence Pharmaceuticals, Inc.***Company▲*

CADX

*Ticker▲*

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The 222 patent is the process patent because the way the free radicals work, you need to have extraordinarily low levels of oxygen for the free radicals to do their job. If you have too much oxygen remaining in your solution and like most pharmaceutical products OFIRMEV is mostly water so there's a lot of oxygen available. If you have too much oxygen remaining in your solution, it overwhelms the free radicals and they can't do their job.

So it's important that you have a process that removes and keeps oxygen from the solution while you're filling these 100 ml bottles with mixed up products so it's a multi set. The machine that actually does, it's bigger than this room so you have a bottle with a big opening that travels through a lot of space that's exposed to a lot of oxygen. And so that process is what's covered in the 222 patent.

So I think the settlement we have with Perrigo – certainly they've acknowledged that their process infringed that process, and that we settle for the December 2020 date.

In addition to the two patents, there's also a substantial amount of manufacturing know-how. It's one thing to know how to do the – to sit down and look at the recipe from the patents. It's another thing to actually do it and we're kind of the poster child for that.

We have two suppliers for OFIRMEV. We have Bristol-Myers Squibb, who have manufactured 600 million doses of IV acetaminophen over the last nine years. Our primary supplier in the US was Baxter, and Baxter so far has yet to manufacture a batch that stays stable long enough to be commercially viable. You may remember we had two recalls this past year of the Baxter product, and they were related to some stability concerns.

And so the two manufacturers that we have, the one that kind of has done it from the beginning, they can do it, and everyone else seems to have trouble with this. And really even knowing all the things there are to know, having full tech transfer from BMS, there's still been a challenge getting the product to be produced in a reliable, stable way at Baxter.

So there's a – you need to know a lot to do this. So just getting it down isn't enough – then you have to figure out how to do it. Which is why us maintaining the option of whether we bring out an authorized generic is important. Because we are only going to bring in authorized generic out if we think someone is imminently going to introduce a generic, but they're going to have to prove to the FDA they can actually do it.

And so far, the generics in Europe have not been particularly successful. And some of those companies have been at it for four years now, trying to supply the market, and they're getting better, but they still have lots of failed batches and product that turns yellow on the shelf, which is a sure indication that you have oxygen in it.

Anyway, a long answer to a short question, but...

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**Traver A. Davis, Analyst, Piper Jaffray, Inc.**

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Let's move on a little bit to the – I guess, more of the commercial metrics for OFIRMEV. Can you walk us through some of the key performance metrics for the product? Maybe specifically, any color on the number of hospitals currently on formularies? Color on total units shipped perhaps in the most recent quarter? And how that's trending so far in the fourth quarter?

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Sure. So we're on formulary now in excess of 2,000 hospitals across the country. I mentioned earlier that we target about 1,800. So we're on more hospital formularies than we target. A lot of that is a result of getting broad formulary acceptance and integrated delivery network that includes small hospitals that we don't necessarily call on.

But the number of hospitals on formulary – and we actually have more than that that order the product. We actually have more than 2,500 hospitals that order the product.

So we're getting broad use that continues to grow. We are not primarily focused on formulary approval these days. We were through the first nine months or ten months of launch, but we've shipped it strictly to pull-through.

The things we look at to measure our progress – we look at obviously sales. We look at vial sales to hospitals. And in fact, that's how we report our sales. We report sales as shipment to hospitals. So we're not reporting sales to wholesalers yet, but we're reporting wholesaler shipments to hospitals. So we're reporting them at the hospital level.

And so we look at the number of orders – so we look at the number of customers ordering the product, and that continues to grow quarter over quarter. We look at the number of times in a quarter those hospitals order. And we look at the size of each of those orders. And all those metrics are growing essentially month-over-month, but importantly, quarter-over-quarter.

There's a national limit to the number of orders per quarter. Most you can have are 13. They only get captured at – even though hospitals can order more than once a week, the data sources only capture a weekly order. So we only know that they ordered that week. We don't know if they ordered three times that week or one time that week.

And it would never be 13, because there are a number of hospitals that order every other week. They tend to order big quantities of product, but they order twice a month. So we'll never, ever get to 13 orders per quarter.

We're at about just over five orders per quarter for hospitals, and moving – we're averaging, per order, just under ten cases per order with 24 vials in a case. And so that's growing.

And like I said, more than 2,500 hospitals ordering the product. Some more consistent than others. And that ranges from hospitals that are ordering hundreds of cases a week down to the hospitals that order a couple of cases a month.

**Traver A. Davis, Analyst, Piper Jaffray, Inc.**

On to pricing, how should we think about pricing going forward? Do you believe that you do have strong pricing power for the product? And I believe you've had some recent price increases. Do they significantly flow through to average selling prices pretty quickly or...

**Theodore R. Schroeder, President, Chief Executive Officer & Director**

It did. We've taken exactly one price increase in July. We took a 6% price increase. Most of that flowed right through.

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We don't pre-announce price increases, so there's very little buy in. In today's world, most companies have wholesaler agreements that we have signed, which essentially prevents them from ordering in, but they do get some benefit for pricing. But we're reporting at the hospital level anyway, so we pretty much captured all the upside for the price increase right away.

And based on the lack of market response to that price increase, we do think that we have more upside for pricing over time. So it will be a component of our marketing as we move forward.

**Traver A. Davis, Analyst, Piper Jaffray, Inc.**

And just a related question on gross margins. How should we think about them trending for 2013?

**Theodore R. Schroeder, President, Chief Executive Officer & Director**

Yes. Well, they should trend up. We were just below 60% in the third quarter. That's right – is that right, Bill? Yes, just below 60% in the third quarter. We expect that will continue to trend up, both from improvements and efficiencies.

One of the things that hit our margin early in the year was our need to switch from sourcing from Baxter to BMS. And because of the recall, we did a lot of air shipments from Italy. You can imagine – and the product flies first class, so it's not cheap to airfreight temperature-controlled products. But we did it to – we really only had about a three-day period of time where we were out of product to ship to customers. And so we were able to recover from that very quickly, but that definitely impacted the margin early in the year.

Now we're on a normal kind of ocean-freight thing, and the cost of shipment has gone way down. We'll see some efficiencies on the manufacturing side. We're able to find some – every couple of pennies you can find in different efficiencies through the supply chain helps, and we're able to take some of those. So over time – and that, with the impact of price increases, we'll see the margin continue to improve.

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Date▲**QUESTION AND ANSWER SECTION**

&lt;Q&gt;: [Question Inaudible] (17:30)

&lt;Q – Traver Davis – Piper Jaffray, Inc.&gt;: Excuse me?

&lt;Q&gt;: [Question Inaudible] (17:33)

<A – Ted Schroeder – Cadence Pharmaceuticals, Inc.>: No, Bristol had – the plant where they manufacture is in Anagni, Italy. So they have don't have a US manufacturing plant that's capable of manufacturing IV acetaminophen. They have a big operation in Italy for this product. And part of the reason they're manufacturing for us is to use the supply.

You might ask but why weren't they the primary supplier when you launched? It's not because we didn't want them to. They weren't willing to do that role. And then suddenly, they had a new CEO, and they had a change of priorities for that manufacturing plant, and they came to us just before approval and wanted to see if they could work out a supply agreement. We were glad to do that, and thank goodness we did because that allowed us to do it.

Unlike Baxter, where we have a single line, Bristol has multiple lines where they can manufacture the product. So even though it's a single manufacturer, they have four or five different lines that they can run the product on. So you'd have to have something catastrophic happen to lose supply at Bristol.

<Q – Traver Davis – Piper Jaffray, Inc.>: Any other questions? Why don't we just move on to maybe a bigger picture question for Cadence?

So you have OFIRMEV as the foundation, but can you talk about some efforts to diversify your product portfolio and perhaps leverage the hospital-based sales organization?

<A – Ted Schroeder – Cadence Pharmaceuticals, Inc.>: Yes, absolutely. We believe we have a tremendous asset in our sales force, a sales force that's demonstrated that they can impact hospitals. Lots of success in formulary approvals, and lots of success in selling OFIRMEV in those institutions. They clearly have capacity to do more things than just OFIRMEV and that's our intent to put more products in there.

So when we think about business development opportunities, we're really thinking about them in kind of short-term and long-term opportunities. In the short-term bucket, we're looking at things that we could put in the sales force right away. Our market products – either co-promotes, in-licensing product, or acquiring a product that would go in there.

And we're looking at smaller products. Probably products with revenues below \$100 million and products that are largely principally sold within the walls of a hospital. Certainly products that are underpromoted are more attractive, because we think with our larger sales force that we can grow many of those products.

So we have a robust deal flow we have right now. We have six opportunities we're looking at, some in each of those categories I described, and more on their way. We get a lot of inbound calls to look at hospital products.

For the moment, we're staying away from products that have a big spend for development. We've recently were very close on an asset that we pulled out of the process, not because it wasn't a good NPV, but because we realized kind of late in the process, after we got full access to diligence, that the organic growth of the all-market product was pretty limited, and that the real opportunity for

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the product was investing in line extensions and other products, which for us, is a challenge in the short term, because that means increasing our cash burn, which we've committed not to do.

So we walked away from that asset. It'll be a good asset for someone. I think interestingly, they're clearly late announcing the deal because it was supposed to be wrapped up a couple of weeks ago, so maybe someone else has figured out the same thing we did.

So maybe they're back. A different structure might work. So maybe they'll come back on that. It's still a product we would like, if we could get the financial structure to work.

So it's an example, but we learned a lot. And what we learned from that process was not only our ability to really assess markets and the team to do that, but we also I think have good confidence that alternative financing, other than just issuing new stock, is available to us, and that we have multiple places we can go to negotiate for some different debt structures to help finance those products.

Longer term, we will look to bring in products that have a development component. We're definitely interested to be a consolidator. It's not lost on us there are a lot of single-product hospital companies. And I think when we get to the right financial stage, we can be the acquirer, because we have the organization to really market the products that these companies would have in the hospitals. So that's further out, but it's there.

And then most of you may know we have a license agreement with a private company, Incline Therapeutics, for their IONSYS device, which is essentially a PCA device but it's not a pump. It's a patch-like device, but it's a patient controlled analgesia device.

I'd put that in the longer-term bucket. We have an option, it sits out there. If they were to file their sNDA next quarter, we probably wouldn't do it, but a year from now, who knows. We'd see where we were financially and make that decision. But it's not something we would do in the short-term.

**<Q – Traver Davis – Piper Jaffray, Inc.>**: And just staying on that, just speak to the current cash position and the cash burn. And do you think that the cash position is sufficient to get you to profitability, or going forward?

**<A – Ted Schroeder – Cadence Pharmaceuticals, Inc.>**: Yeah. We ended the third quarter with \$72 million, and that's enough – \$75 million, sorry. I didn't pay Bill his bonus, so I saved \$3 million. He doesn't get \$3 million. Just kidding for those of you dialing in.

We have \$75 million on the balance, and that is enough to get us to cash flow breakeven. We're committed that that'll get us there.

So I had somebody a couple of weeks say well, sales suddenly flat and then you'll be in trouble and well, that's true. But hey, I don't see that happening and in fact I see the opposite happening. But even if that were to happen, we would make the adjustments in the business to be sure that we got to cash flow breakeven with the cash we have. So, we're...

**<Q – Traver Davis – Piper Jaffray, Inc.>**: Great. So I think we're just running up on time. But Ted, thanks very much for being with us today.

**<A – Ted Schroeder – Cadence Pharmaceuticals, Inc.>**: Thank you, Traver. Thanks.



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